



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,766	09/28/2001	Helmut Meissner	1/1150	3427

28501 7590 11/26/2002

BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877

EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,766

Applicant(s)

MEISSNER ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 and 36-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 19-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Claims 1-40 are pending. In response to the Restriction requirement, applicant has elected the invention of group I, claims 1-12, 19-35. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-18, 36-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

2. The rejection for Claims under 35 U.S.C. 112, second paragraph is withdrawn because the amendment has obviated the rejection.

Claim Rejections - 35 USC § 102

3. The rejection for Claims 1-12, 19-30 under 35 U.S.C. 102(b) as being anticipated by Banholzer (WO 92/16528, PTO-1449) is withdrawn because the claims have been amended to exclude the prior art compound.

4. The rejection for Claims 31-35 under 35 U.S.C. 102(b) as being anticipated by Emran is withdrawn because the claims have been amended to exclude the prior art compound.

5. The rejection for Claims 31-33 under 35 U.S.C. 102(b) as being anticipated by Zakharova is withdrawn because the claims have been amended to exclude the prior art compound.

Double Patenting

6. The provisional rejection for Claims 1-12, 19-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending

Art Unit: 1625

Application No. 09/976950 in view of Banholzer (WO 92/16528, PTO-1449) is withdrawn because a terminal disclaimer has been filed in 09/976950, thereby obviating the rejection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banholzer I (5770738) or II (5654314, which has the same parent as 5770738), which are the US equivalents of WO 92/16528 (PTO-1449). The dehydro-tropanyl compound and its method of use are claimed in 5770738 (columns 23-24, claims 1-14), while the epoxy-tropanyl compound, its composition and method of use are claimed in 5654314 (columns 25-26, claims 1-10). The references made to Banholzer I therefore is also applicable to Banholzer II.

Banholzer I generically discloses esters of bi- and tricyclic amino alcohols for use as an anticholinergic agent (columns 1-5), which encompass the instant compound. Specific compounds are described on column 12, Table II, compounds 5, and 10.

Banholzer's compounds 5, and 10 differ from the instant in not having a substituent on the phenyl.

Banholzer, however, teaches that substituent(s) on the phenyl, such as F of the instant claim 6, is an optional choice (column 3, lines 24-25). An example of fluoro-phenyl is shown in Table V (column 13, Example 8).

At the time of the invention, one of ordinary skill in the art would be motivated to add the alternative, exemplified, substituent on the phenyl of Banholzer's compound to arrive at the instant invention, with the reasonable expectation of obtaining an additional compound with anticholinergic activity, since Banholzer had clearly taught that any species within the disclosed genus, especially the exemplified compounds, would be effective as anticholinergics.

Art Unit: 1625

The compound of instant claims 31-35 has $-N-R^1$ instead of the prior art $R^2-N^+-R^1$ in the tropanyl. However, they are interchangeable groups (column 2, lines 40-50).

At the time of the invention, one of ordinary skill in the art would be motivated to replace the quaternary group with the interchangeable tertiary group in the tropanyl of Banholzer's compound to arrive at the instant invention, with the reasonable expectation of obtaining an additional compound with anticholinergic activity, since Banholzer had clearly taught that any species within the disclosed genus, especially the exemplified compounds, would be effective as anticholinergic.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 19-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5770738 and claims 1-10 of U.S. Patent No. 5654314 for reasons set forth in paragraph 7 above.

Conclusion

9. No claims are allowed.

Art Unit: 1625

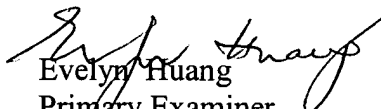
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang
Primary Examiner
Art Unit 1625

November 18, 2002